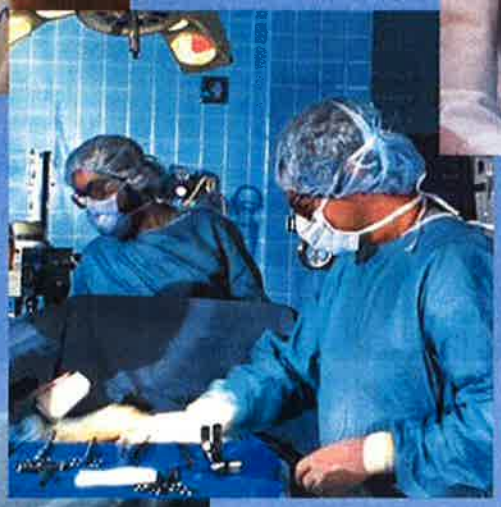
The 2004 joint report issued by the Federal Trade Commission and the Department of Justice, *Improving Health Care: A Dose of Competition*, is a 361-page report. We have included only the relevant chapter relating to Certificate of Need regulation, as critiqued by the American Health Planning Association in January 2005. You can obtain a copy of the full report by accessing the following link:

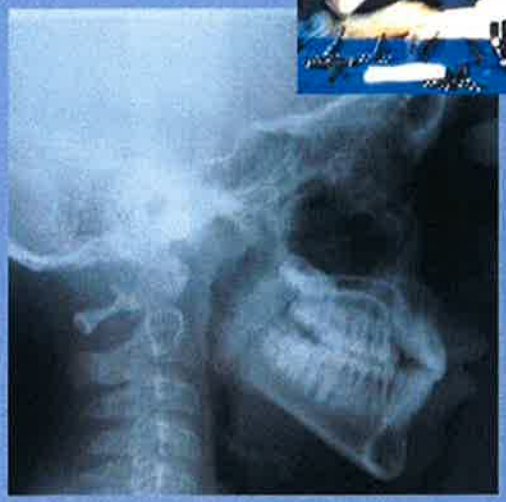
https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice

DEPARTMENT OF JUSTICE

FEDERAL TRADE COMMISSION

Improving Health Care: A Dose of Competition





A Report by the Federal Trade Commission and the Department of Justice

July 2004

CHAPTER 8: MISCELLANEOUS SUBJECTS

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I. CERTIFICATES OF NEED

Introduction. State certificate of need (CON) programs generally prevent firms from entering certain areas of the health care market unless they can demonstrate to state authorities that there is an unmet need for their services. Upon making such a showing, prospective entrants receive from the state a CON allowing them to proceed.[1] Proving that unmet need to state authorities is sometimes expensive and time-consuming.[2] Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke on the subject of CON at the Hearings on a panel discussing Quality and Consumer Protection: Market Entry (June 10).[3]

Many CON programs trace their origin to a repealed federal mandate. The National Health Planning and Resources Development Act of 1974[4] offered states powerful incentives to enact state laws implementing CON programs.[5] By 1980, all states except Louisiana had enacted CON programs.[6] Congress repealed the federal law in 1986, but a substantial number of states continue to maintain CON programs,[7] "although often in a loosened form compared to their predecessors."[8]

The Agencies believe that CON programs can pose serious competitive concerns that generally outweigh CON

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[1] *See* JOHN MILES, 2 HEALTH CARE & ANTITRUST LAWS: PRINCIPLES AND PRACTICE § 16:1, at 16-2, 16-5 to 16-6 (2003) (noting that CONs under the federal Health Planning Act required providers to "obtain state approval – a 'certificate of need' – before spending set amounts on capital investments or adding new health care services"); James F. Blumstein & Frank A. Sloan, *Health Planning and Regulation Through Certificate of Need: An Overview*, 1978 UTAH L. REV. 3; Randall Bovbjerg, *The Importance of Incentives, Standards, and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83; Clark C. Havighurst, *Regulation of Health Facilities and Services by "Certificate of Need"*, 59 VA. L. REV. 1143 (1973).

[2] *See* Keith B. Anderson, Certificate of Need Regulation of Health Care Facilities, FTC Staff Prepared Statement Before North Carolina State Goals and Policy Board 7 n.17 (Mar. 6, 1989).

[3] Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf.

[4] Pub. L. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5), *repealed*, Pub. L. 99-660, § 701, 100 Stat. 3799 (1986).

[5] MILES, *supra* note 1, § 16:1, at 16-2.

[6] *See, e.g.*, Morrisey 6/10 at 146; *On Certificate of Need Regulation: Hearing on H.B. 332 Before the Senate Comm. On Health and Human Services* (Ohio 1989) (Statement of Mark D. Kindt, FTC Regional Director) (noting that by 1980, all states except Louisiana had enacted CON legislation) [hereinafter Kindt].

[7] *See* Davenport-Ennis 5/29 at 113-14; Morrisey 6/10 at 146 (noting that by 2002, about 36 states and the District of Columbia retained CON programs in some form); MILES, *supra* note 1, § 16:2, at 16-9 (stating that "CON laws remain in many states and the District of Columbia"). Quite recently, Florida exempted from CON new adult open-heart surgery and angioplasty programs at general hospitals and the addition of beds to existing hospital structures. Fla. Bill SJ 01740 (effective July 1, 2004), *amending* FLA STAT. ch. 408.036, .0361 (2003).

[8] MILES, *supra* note 1, § 16:1, at 16-2 to 16-3. *See also* Len M. Nichols et al., *Are Market Forces Strong Enough to Deliver Efficient Health Care Systems? Confidence is Waning*, 23 HEALTH AFFAIRS 1, 11 (Mar./Apr. 2004) (noting that CON programs "eroded through the 1990s").

programs' purported economic benefits. Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns. The Report analyzes each of these points in turn below.

A. Rationale Behind CON Programs

CON programs had the major goal of controlling costs by restricting provider capital expenditures.[9] The forces of competition ordinarily limit excess supply, but, according to a panelist representing the American Health Planning Association, "[c]ompetition in health care is ... very different" than in other markets.[10] Congress appears to have shared this view in 1974; the passage of the Health Planning Act reflected a congressional belief that market failure plagued the health care market, resulting in "excess supply and needless duplication of some services."[11]

The system of cost-based reimbursement may have driven the problem that Congress sought to solve.[12] When many CON programs were established, government or private insurance paid health care expenses "on a retrospective cost reimbursement basis."[13] This, coupled with the general concern that patients would not be sufficiently price sensitive and would demand the perceived highest quality services, led to the fear that health care providers would expand their services – sometimes to the point of offering unnecessarily duplicative services – because they competed largely on only non-price grounds.[14]

Although cost-based reimbursement is much less common today, some contend that CON programs still have a role to play in the health care marketplace. Indeed, one panelist argued that in health care markets, "providers control the supply of services. Medical practitioners direct the flow of patients and therefore the demand for

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[9] *See* Piper 6/10 at 53; Morrisey 6/10 at 146 (noting that CON programs "were established in the '70s to help control health care costs"). *See also* MILES, *supra* note 1, § 16:1, at 16-4 ("[The primary role of the Health Planning Act was to regulate the supply of health care resources, particularly institutional services, by requiring a CON from the state before certain levels of capital expenditures could be made or new services introduced."); Kindt, *supra* note 6, at 2-3 (noting that a "key justification" for CON programs has been "the belief that health care providers, particularly hospitals, would undertake excessive investment in unregulated health care markets," driving up health care costs); PUBLIC HEALTH RESOURCE GROUP, CERTIFICATE OF NEED PROJECT REPORT 17-18 (2001).

[10] Piper 6/10 at 53-54 (observing that the main aim of CON programs is to limit "excess supply generating excess demand"). *See also* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 18.

[11] MILES, *supra* note 1, § 16:1, at 16-4.

[12] *See id.*

[13] Anderson, *supra* note 2, at 6. *See also* Davenport-Ennis 5/29 at 114 (noting that at the time, the federal government reimbursed health care expenses on a "cost-plus basis, which did not provide the cost control capability of today's prospective payment system").

[14] Morrisey 6/10 at 147; *see also* Davenport-Ennis 5/29 at 114 (noting that government officials intended CON to "retain rising health care costs, to prevent unnecessary duplication of resources and services, and [to] expand consumer access to quality health care services").

services."[15] In health care markets, he stated, "supply generates demand[,] putting traditional economic theory on its head."[16] Moreover, consumers lack the information to compare prices, he said.[17] Such problems can lead to an inefficient allocation of health care resources and higher health care costs, some state.[18]

Some commentators also suggest that CON programs can enhance health care quality and access.[19] One panelist, for example, stated that there are "few mechanisms" other than the CON process that promote "minimum patient volumes" that contribute, he stated, to better quality care.[20] CON regulation also can address cherry picking, preventing firms from, for example, converting cancer "medical practices to medical care facilities [that] divert well-insured patients [from] local hospital cancer programs" and "undermine[] the ability of essential community hospitals to provide a full array of oncology services to the entire community."[21]

B. Competitive Concerns that CON Programs Raise

Many have criticized CON programs for creating barriers to entry in the health care market.[22] As noted previously, CON

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[15] Piper 6/10 at 55.

[16] *Id.* at 62.

[17] *Id.* at 55 (noting, however, that consumers do "suffer under the ultimate increased costs in premiums and their taxes"). The same panelist also cited empirical studies suggesting that CON programs reduce health care costs, studies that another panelist questioned. *Compare* Piper 6/10 at 57-61, *and* Thomas R. Piper, *Comments Regarding Hearings on Health Care and Competition Law and Policy* 5-13 (Public Comment) (discussing these and other studies) [hereinafter Piper (public cmt)], *with* Loeffler 6/10 at 127 (questioning those studies), *and with* Piper 6/10 at 127-28 (responding to such questions). *See generally infra* notes 37-42, and accompanying text.

[18] *See, e.g.*, MILES, *supra* note 1, § 16:1, at 16-4 (describing Congress' concerns); Piper 6/10 at 62 (asserting that "[a]reas with more hospitals and doctors spend more on health care services per person"); PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 11 ("Adding providers usually mean increases in costs."); *see also* Piper 6/10 at 126 (noting that the fact that the public fisc is at stake adds importance to the concern).

[19] PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 5.

[20] Piper (public cmt), *supra* note 17, at 12 (noting, for example, that in CON-free states, "the percentage of patients that had surgery in low volume programs was three times higher than in states with CON regulation").

[21] Piper (public cmt), *supra* note 17, at 13-14; *see also* Piper 6/10 at 54 (noting that CON programs aim to overcome "market gaps and excesses like the avoidance of low-income populations and concentration of services in ... affluent areas"); Nichols et al., *supra* note 8, at 11 (stating that today "some states are considering reinstituting or reinvigorating [CON programs] in response to construction of physician-owned specialty facilities, which has posed a competitive threat to community hospitals"). *But see* Price 6/10 at 108 (would-be entrant denying allegation of "cherry picking"); Davenport-Ennis 5/29 at 115-16 (stating that CON programs restrict the supply of cancer treatment services such that "low-income, seriously ill, and rural patients" who do not live near a hospital or major medical center lose access to care).

[22] *See* Anderson, *supra* note 2, at 7; Hennessy 6/10 at 95, 99-100 ("CON protects incumbent providers . . . from competition" and is an "impediment to innovation [and] quality improvement" in health care); Blumstein & Sloan, *supra* note 1; Bovbjerg, *supra* note 1; Havighurst, *supra* note 1. The Commission has also noted the

regimes prevent new health care entrants from competing without a state-issued certificate of need, which is often difficult to obtain. This process has the effect of shielding incumbent health care providers from new entrants. As a result, CON programs may actually increase health care costs, as supply is depressed below competitive levels.[23]

Moreover, CON programs can retard entry of firms that could provide higher quality services than the incumbents.[24] By protecting incumbents, CON programs likewise can "delay[] the introduction and acceptance of innovative alternatives to costly treatment methods."[25] Similarly, CON programs' "[c]urtailing [of] services or facilities may force some consumers to resort to more expensive or less-desirable substitutes, thus increasing costs for patients or third-party payers. For example, if nursing home beds are not available, the discharge of patients from more expensive hospital beds may be delayed or patients may be forced to use nursing homes far from home."[26]

Empirical studies indicate that CON programs generally fail to control costs and can actually lead to increased prices.[27] Supporting this conclusion, some panelists offered examples of the anticompetitive effects of CON programs. One panelist, for example, noted that CON programs "artificially limit[]" access to cancer treatment, placing "vital therapies and technologies out of [consumers'] reach" in favor of "old technologies."[28] He stated that his practice's application to a state for a certificate of need to introduce improved cancer radiation technology faced opposition in June 2002 from all of the state's operators of existing radiation therapy equipment. One year later, at the time of his testimony in the Hearings, he noted that the state still had not approved the CON application.[29] By contrast, in a bordering state without a CON program, his practice was able to introduce new cancer-fighting technologies rapidly.[30] Another panelist stated that incumbent home health service providers in her state have, for 23 years, successfully opposed the CON application of her nursing service, thereby barring its entry and "keep[ing] the oligopoly in place."[31] The incumbents, she

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impact of CON programs on entry and firm behavior. *See In re* Hosp. Corp. of Am., 106 F.T.C. 361, 489-501 (1985).

[23] *See* Anderson, *supra* note 2, at 7-8; Kindt, *supra* note 6, at 6-7.

[24] *See, e.g.*, Anderson, *supra* note 2, at 7-9; Kindt, *supra* note 6, at 6; *Hosp. Corp. of Am.*, 106 F.T.C. at 495 (opinion of the Commission) (stating that "CON laws pose a very substantial obstacle to both new entry and expansion of bed capacity in the Chattanooga market" and that "the very purpose of the CON laws is to restrict entry").

[25] Anderson, *supra* note 2, at 9; Kindt, *supra* note 6, at 6.

[26] Kindt, *supra* note 6, at 7.

[27] *See generally infra* notes 37-42, and accompanying text.

[28] Hennessy 6/10 at 92-93.

[29] *Id.* at 95-96; *see also id.* at 96-97 (noting similar opposition to application to introduce PET scanning to state with CON program).

[30] *Id.* at 95-98, 136.

[31] Price 6/10 at 101-10.

stated, charge more for comparable services than her service would.[32] The barrier to entry has likewise shielded incumbents from the need to offer improved and innovative services, she said.[33] As a result, some patients resort to services that "are not to their liking" or simply are not served at all.[34] Other panelists described how an incumbent used the CON process as a barrier to entry in a local surgical market,[35] and how a CON program restricted supply in a way that jeopardized patients' care.[36]

C. CON and Cost Control

Several panelists and commentators stated that CON programs generally fail to control costs.[37] Indeed, one panelist surveyed the empirical literature on the economic effects of CON programs and concluded that the "literature tends to conclude ... that CON has been ineffective in controlling hospital costs," and that, to the contrary, "[i]t may have raised costs and restricted entry."[38] Commentators stated that the reason that CON has been ineffective in controlling costs is that the programs do not put a stop to "supposedly unnecessary expenditures" but "merely redirect[] any such expenditures into other areas."[39] Thus, a CON rule that restricts capital investment in new beds does nothing to prevent

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[32] *Id.* at 105.

[33] *Id.* at 106.

[34] *Id.* at 102, 104 (reporting that she has spoken to "young people who have been lying in their own waste for three days with no one to come take care of them").

[35] Rex-Waller 3/27 at 58.

[36] Davenport-Ennis 5/29 at 115-21.

[37] *See* Hennessy 6/10 at 93-94 (stating that "CON is a failure as a cost containment tool" and that the premiums in Kansas and Missouri are generally the same, in spite of the fact that one state has a CON program and the other does not); Anderson, *supra* note 2, at 2-6 (summarizing empirical evidence and finding that CON fails to regulate costs); Kindt, *supra* note 6, at 3-5 (summarizing empirical studies on the economic effects of CON programs and concluding that "[t]here is near universal agreement among the authors [of studies on the economic effects of CON programs] and other health economists that CON has been unsuccessful in containing health care costs"); DANIEL SHERMAN, FEDERAL TRADE COMM'N, THE EFFECT OF STATE CERTIFICATE-OF-NEED LAWS ON HOSPITAL COSTS: AN ECONOMIC POLICY ANALYSIS (1988) (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data, that strong CON programs do not lead to lower costs but may actually increase costs); MONICA NOETHER, FEDERAL TRADE COMM'N, COMPETITION AMONG HOSPITALS 82 (1987) (empirical study concluding that CON regulation led to higher prices and expenditures); KEITH B. ANDERSON & DAVID I. KASS, FEDERAL TRADE COMM'N, CERTIFICATE OF NEED REGULATION OF ENTRY INTO HOME HEALTH CARE: A MULTI-PRODUCT COST FUNCTION ANALYSIS (1986) (economic study finding that CON regulation led to higher costs, and that CON regulation did little to further economies of scale); *cf.* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 4 (noting that the "track record of the cost effectiveness of state CON programs is decidedly mixed," and that "[i]n some states, the of effectiveness is at least partially attributable to deficiencies in program operations and to political environments in which legislative or high-level executive branch intervention alters or affects CON decision-making"). *See also* David S. Salkever, *Regulation of Prices and Investment in Hospitals in the United States*, *in* 1B HANDBOOK OF HEALTH ECONOMICS, 1489-90 (A.J. Culyer & J.P. Newhouse eds., 2000) (concluding that "there is little evidence that [1970s-era] investment controls reduced the rate of cost growth," even though "inconsistent reports of constraining effects on numbers of beds and diffusion of some specialized services did appear").

[38] Morrisey 6/10 at 148-49, 152-53.

[39] Kindt, *supra* note 6, at 5.

hospitals from "add[ing] other kinds of fancy equipment" and using that to compete for consumers.[40]

As one commentator noted, "[t]he regulation of supply through mechanisms such as CON may have made sense when most reimbursement was cost-based and thus there was incentive to expand regardless of demand but they make much less sense today when hospitals are paid a fixed amount for services and managed care forces them to compete both to participate in managed-care networks and then for the plans' patients."[41] The policy justification of CON programs is particularly questionable given the number of evolving supply and demand-side strategies for controlling costs, including those outlined in Chapter 1.[42]

Conclusion. The Agencies believe that CON programs are generally not successful in containing health care costs and that they can pose anticompetitive risks. As noted above, CON programs risk entrenching oligopolists and eroding consumer welfare. The aim of controlling costs is laudable, but there appear to be other, more effective means of achieving this goal that do not pose anticompetitive risks. A similar analysis applies to the use of CON programs to enhance health care quality and access. For these reasons, the Agencies urge states with CON programs to reconsider whether they are best serving their citizens' health care needs by allowing these programs to continue.

II. STATE ACTION AND NOERR DOCTRINES

The state action and Noerr-Pennington doctrines curb competition law in order to promote important values, such as federalism and the right to petition the government for redress of grievances.[43] Inappropriately broad interpretations of these doctrines, however, can chill or limit competition in health care markets.[44] Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing Competition Law and Noerr Pennington/State Action issues on June 11.[45]

A. State Action Doctrine

The state action doctrine precludes federal antitrust scrutiny of certain state (and state authorized) conduct. The state action doctrine is rooted in principles of federalism and respect for state sovereignty. As the Supreme Court stated in the seminal state

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[40] *Id.*

[41] MILES, *supra* note 1, § 16:1, at 16-3.

[42] *See, e.g.*, Kindt, *supra* note 6, at 8-11; Anderson, *supra* note 2, at 9-13 (same); Davenport-Ennis 5/29 at 121 (citing means other than CON programs "to regulate over-usage and over-referral"). *But see* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 11 (stating that "[m]anaged care companies have not created the competition and lower cost solutions originally expected of them").

[43] *See* Havighurst 6/11 at 30-32.

[44] *See, e.g.*, Robin E. Remis, *Health Care and the Federal Antitrust Laws: The Likelihood of a Harmonious Coexistence*, 13 J. CONTEMP. HEALTH L. & POL'Y 113, 123-25 (1996).

[45] Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf.

action case, neither the Sherman Act nor its history suggests that Congress intended the antitrust laws to "restrain a state or its officers or agents from activities directed by the legislature."[46]

The state action doctrine shields activities of the state when it is acting in its sovereign capacity, and actions of most other entities and individuals if they are acting in furtherance of a clearly articulated state policy and are actively supervised by the state.[47] The clear articulation requirement "ensures that these entities may use anticompetitive mechanisms only if those mechanisms operate because of a deliberate and intended state policy."[48] Similarly, the active supervision requirement "ensures that the entities are acting pursuant to state policy, not their own private interests ...."[49]

One panelist noted that antitrust law is unsettled as to whether state regulatory commissions and licensing boards must satisfy both of these requirements.[50] The issue is better formulated as whether regulatory commissions and licensing boards that are substantially controlled by incumbent providers are really state actors, rather than private entities, for purposes of assessing state action. When providers substantially control a regulatory commission or licensing board, there are good reasons to require satisfaction of both the clear articulation and active supervision requirements of the state action doctrine.[51]

The Agencies have long opposed improper extensions of the state action doctrine. Unfortunately, some courts have broadly interpreted the "clear articulation" and "active supervision" requirements in

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[46] Parker v. Brown, 317 U.S. 341, 350-51 (1943).

[47] *See, e.g.*, Town of Hallie v. City of Eau Claire, 471 U.S. 34, 40 (1985) (holding that a municipality engaging in activity pursuant to state policy qualifies as state action and no active supervision required); Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 U.S. 97, 105 (1980) (stating that "the challenged restraint must be one clearly articulated and affirmatively expressed as state policy [and that] the policy must be actively supervised by the State itself") (internal quotation marks and citation omitted). *See also* discussion in OFFICE OF POLICY PLANNING, FEDERAL TRADE COMM'N, REPORT OF THE STATE ACTION TASK FORCE 1 (2003) [hereinafter FTC, STATE ACTION REPORT], *available at* http://www.ftc.gov/os/2003/09/stateactionreport.pdf; James F. Blumstein & Terry Calvani, *State Action as a Shield and a Sword in a Medical Services Antitrust Context:* Parker v. Brown *in Constitutional Perspective*, 1978 Duke L.J. 389.

[48] FTC, STATE ACTION REPORT, *supra* note 47, at 1.

[49] *Id.* The active supervision requirement similarly ensures that there is actual (and not simply nominal) oversight by the state.

[50] *See* Andrus 6/11, at 52 ("For licensing boards, the Midcal test – because licensing boards are quasi-state agencies or entities, it's not absolutely clear whether they need to satisfy both prongs of Midcal ... We know that they have to satisfy the first prong of Midcal, that is, the clear articulation prong.").

[51] *See* FTC, STATE ACTION REPORT, *supra* note 47, at 15 ("[T]he active supervision test is applied when the Court deems there to be an appreciable risk that the challenged conduct may be the product of parties pursuing their own interests rather than state policy."); Einer Elhauge, *The Scope of Antitrust Process,* 104 HARV. L. REV. 668, 688 (1991) ("[F]inancially interested actors cannot be trusted to decide which restrictions on competition advance the public interest; politically accountable actors can.").

ways that sweep more broadly than necessary to protect the interests of federalism.[52] Health care has not been immune to these overly broad interpretations.[53]

Panelists cited specific areas in which entities might improperly invoke the state action doctrine to shield anticompetitive conduct in health care markets, including: (1) efforts by the medical staff of public hospitals to withhold staff privileges from rival health care providers;[54] (2) state efforts to sanction hospital mergers without federal antitrust review;[55] and (3) private efforts to use state agencies' frequent reliance on private credentialing bodies to raise barriers to entry or otherwise limit competition.[56]

The Commission has an ongoing advocacy role in encouraging states to consider the competitive implications of proposed legislation. For example, state legislators have asked the Commission to comment on draft legislation that would shield physicians from antitrust liability for collective bargaining. Commission staff have responded by noting that "an antitrust exemption (i) would authorize physician price fixing, which is likely to raise costs and reduce access to care; and (ii) would *not* improve the quality of care, which can be accomplished through less anticompetitive means."[57] State reaction to Commission advocacy on this point has been "varied but, in large part, positive."[58]

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[52] FTC, STATE ACTION REPORT, *supra* note 47, at 25-49; Delacourt 6/11 at 8, 134.

[53] *See* Jackson v. W. Tennessee Healthcare, Inc., 2004 U.S. Dist. LEXIS 4571 (W.D. Tenn. 2004); Crosby v. Hosp. Auth. of Valdosta, 93 F.3d 1515, 1532 (11th Cir. 1996) (stating that "clear articulation" test requires "only that the anticompetitive conduct be reasonably anticipated, rather than the inevitable, ordinary, or routine outcome of a statute") (quoting FTC v. Hosp. Bd. of Dir. of Lee County, 38 F.3d 1184 (11th Cir. 1994)); Martin v. Mem'l Hosp. at Gulfport, 86 F.3d 1391 (5th Cir. 1996). *See also* FTC, STATE ACTION REPORT, *supra* note 47, at 29-33.

[54] Havighurst 6/11 at 40.

[55] *Id.* at 44-45.

[56] *Id.* at 46-48 (asserting that "[t]he pharmacy profession has succeeded over the last ten years in raising the minimum training for pharmacists from five to six years," resulting in "a huge shortage of pharmacists" and cost increases); Lyon 6/11 at 60-70 (arguing that a private, national nursing organization has persuaded state nursing boards to raise barriers to entry to the nursing profession by adding certain certification or licensing requirements); McClure 6/11 at 91-94, 112-13 (arguing that the American Dental Association has persuaded some state dental boards to pursue disciplinary action against dentists who advise their patients to have fillings made with amalgam containing mercury removed).

[57] FTC, STATE ACTION REPORT, *supra* note 47, at 67, *citing* Letter from Richard A. Feinstein, Assistant Director, Federal Trade Commission, to Robert R. Rigsby, District of Columbia Office of Corporation Counsel (Oct. 29, 1999) (regarding Bill No. 13-333), *at* http://www.ftc.gov/be/hilites/rigsby.htm; *Prepared Statement Concerning the "Quality Health-Care Coalition Act of 1999": Hearing on H.R. 1304 Before the House Comm. on the Judiciary*, 106th Cong. 5 (1999) (Statement of Robert Pitofsky, Chairman, Federal Trade Commission), *at* http://www.ftc.gov/os/1999/06/healthcaretestimony.htm; Letter from William J. Baer, Director, Federal Trade Commission, to Rene O. Oliveira, Texas House of Representatives (May 13, 1999) (regarding Senate Bill 1468), *at* http://www.ftc.gov/be/v990009.htm.

[58] FTC, STATE ACTION REPORT, *supra* note 47, at 67. One panelist explicitly supported the FTC's competition advocacy on this issue.

Likewise, the Commission recently issued a report on competition in the market for online contact lens sales.[59] The report recommends that states considering regulating the sellers of replacement lenses assess the competitive effects of their actions. Specifically, it cautions that "requiring a professional license to sell replacement contact lenses over the Internet is likely to raise prices and/or reduce convenience to consumers without substantially increasing health protections."[60]

The report noted that "consumers can often achieve significant savings by purchasing replacement lenses from sellers other than their eye care providers," including from online vendors.[61] The report recognized, however, that patients could hurt their eyes by getting and wearing replacement contact lenses without a valid prescription, and that requiring patients to have valid prescriptions for their replacement lenses induces them to get regular eye exams.[62] Imposing a prescription requirement for contact lens sellers, the report noted, thus may make sense.[63]

The critical policy question is whether additional state regulation – particularly regulation requiring contact lens sellers to have a state professional license, such as an optician's license – is likely to hurt, or help, consumer welfare. Although such a licensing requirement may afford some consumer benefits, those benefits may be available through other, less restrictive means, and the extra regulation may "induce Internet sellers to charge higher prices or exit the market entirely, harming consumers."[64] Indeed, the resulting increase in price or curtailed convenience in ordering replacement lenses might lead some to "over-wear their lenses or forgo replacement lenses altogether."[65] For these reasons, the report urged state decision-makers to carefully tailor their regulatory efforts in this area to promoting consumer welfare, without enacting unnecessary licensing requirements that could drive low-cost Internet sellers from the market.[66]

The Agencies have extensive experience with the state action doctrine in health care cases. As Chapter 2 reflects, a case implicating the state action doctrine is currently pending in administrative litigation.[67] As Chapter 1 similarly reflects,

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Havighurst 6/11 at 46.

[59] *See* FEDERAL TRADE COMM'N, POSSIBLE ANTICOMPETITIVE BARRIERS TO E-COMMERCE: CONTACT LENSES (2004), *available at* http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf. The report followed a 2002 public workshop on possible barriers to competition in e-commerce markets in contact lenses and nine other industries. *Id.* at 2-3.

[60] *Id.*

[61] *Id.* at 13.

[62] *Id.* at 9.

[63] *Id.* at 15-16.

[64] *Id.* at 22-23.

[65] *Id.* at 23.

[66] *See* also *supra* Chapter 2 (noting similar considerations apply to telemedicine).

[67] *See In re* S.C. State Bd. of Dentistry, No. 9311, http://www.ftc.gov/os/adjpro/d9311/index.htm.

the Agencies have jointly filed amicus briefs regarding the scope of the state action doctrine in several health care antitrust cases. Deciding one of these cases en banc, the Fifth Circuit made clear that courts should not "infer ... a policy to displace competition from naked grants of authority" that serve as "the enabling statutes by which myriad instruments of local government across the country gain basic corporate powers."[68] To do otherwise would extend *Parker* "downward, contrary to the teaching that local instruments of government are subject to the Sherman Act."[69]

B. Noerr-Pennington Doctrine

The First Amendment protects the right to petition the government for redress of grievances. Informed by that Amendment, the *Noerr* doctrine immunizes petitioning from scrutiny under the Sherman Act, even when such petitioning is done "to restrain competition or gain advantage over competitors."[70] By shielding individuals' rights to petition the government for redress of grievances, *Noerr* acts as an "important limitation on the antitrust laws."[71]

Some courts have read this doctrine too broadly. One important limitation on the *Noerr* doctrine relates to the definition of "petitioning the government." The *Noerr* doctrine does not cover every communication to the government. Rather, *Noerr* properly shields conduct directed toward obtaining discretionary governmental action.

The Commission has urged this point in a case involving health care. As *amicus curiae* in *In re Buspirone*, the Commission successfully persuaded the court that a drug manufacturer's listing of a patent in the Food and Drug Administration's "Orange Book" involves no discretionary government decision or action for which a drug manufacturer "petitions," and thus does not enjoy *Noerr* protection.[72] In that case, Bristol-Myers Squibb (BMS) had allegedly foreclosed competition on one of its drugs by improperly submitting patents for listing in the Food and Drug Administration's (FDA) Orange Book. Under the Drug Price Competition and Patent Term Restoration Act,[73] known popularly as the Hatch-Waxman Amendments, innovator drug companies that list their drug patents in the FDA's Orange Book could, under certain

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[68] Surgical Care Ctr. of Hammond v. Hosp. Serv. Dist. No. 1 of Tangipahoa Parish, 171 F.3d 231, 236 (5th Cir. 1999).

[69] *Id.*

[70] Andrx Pharm. v. Biovail, 256 F.3d 799, 817 (D.C. Cir. 2001), *cert. denied,* 122 S. Ct. 1305 (2002). The doctrine is named for the seminal cases that treated it: Eastern R.R. Presidents Conference v. Noerr, 365 U.S. 127 (1961), and United Mine Workers v. Pennington, 381 U.S. 657 (1965).

[71] *Prepared Statement: Hearing on Generic Pharmaceuticals Before the S. Comm. on Commerce, Sci., and Transp.*, 107th Cong. 5 (2002) (Statement of Timothy J. Muris, Chairman, Federal Trade Commission), *at* http://www.ftc.gov/os/2002/04/pharmtestimony.htm; *see also* Delacourt 6/11 at 18 (noting that goal of Noerr doctrine is to "prevent antitrust enforcement from halting or even chilling legitimate political conduct").

[72] *In re* Buspirone Patent Litigation, 185 F.Supp.2d 363, 369 (S.D.N.Y. 2002).

[73] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)), amending the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 52-675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397)).

circumstances, automatically win a stay of FDA approval of any generic rival to that drug for up to 30 months.[74] BMS argued that its submission of patent information for listing in the Orange Book was a petitioning of the government and was thus immune from antitrust review under *Noerr*.[75] As the Commission noted in its *amicus* brief, however, a company's Orange Book filing constitutes the formulaic provision of data in a manner that is informational and mechanical. The FDA, in turn, lists the provided data in the Orange Book in a manner that is purely ministerial. The court thus found that Orange Book listings are as ministerial as tariff filings, which have routinely been held to fall outside the scope of *Noerr* immunity.[76]

Likewise, in the Commission's independent action against BMS, the Commission alleged *inter alia* that BMS "abus[ed] FDA regulations to block generic entry; ma[de] false statements to the FDA in connection with listing patents in the Orange Book; engag[ed] in inequitable conduct before the U.S. Patent and Trademark Office to obtain patents; and fil[ed] baseless patent infringement suits."[77] The Commission stated that BMS's conduct fell outside the scope of *Noerr*. Among other reasons for this conclusion, the Commission noted that "just as the repeated filing of lawsuits brought without regard to the merits, and for the purpose of using the judicial process (as opposed to the outcome of the process), warrants rejection of *Noerr* immunity, so too do the alleged repeated filing of patents on the Orange Book without regard to their validity, enforceability, or listability; repeated filing of recklessly or deliberately false statements with government agencies; and filing of lawsuits brought with or without regard to the merits, also cause the actions challenged here to fall outside the scope of *Noerr*'s protection."[78]

Conclusion. The state action and *Noerr* doctrines play important roles in promoting such values as federalism and the right to petition the government for redress of grievances. Taken too far, these doctrines can impede efforts to maintain vigorous competition in the health care field. The Agencies will continue to advocate in all appropriate venues for interpretations of these doctrines that are consistent with the principles that justify the doctrines in the first place.

III. LONG-TERM CARE

Introduction. Long-term care facilities play an important role in our health care system. Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing Competition Law and Long Term Care/Assisted Living Facilities issues on

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[74] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

[75] *See Buspirone*, 185 F.Supp.2d at 369.

[76] *See id.* at 371.

[77] *See* Federal Trade Comm'n, Analysis to Aid Public Comment: *In re* Bristol-Myers Squibb Company, *at* http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm. The matter was settled by consent decree. *See In re* Bristol-Myers Squibb, No. C-4076 (Mar. 7, 2003) (agreement containing consent order), *available at* http://www.ftc.gov/os/2003/03/bristolmyersconsent.pdf.

[78] FTC, Analysis to Aid Public Comment, *supra* note 77.

June 11.[79]

Several forces drive the market for long-term care, including the aging of the population, growing consumer awareness, restrictions on entry imposed by CON, and changing consumer preferences.[80] Various long-term care options are available, including nursing homes, assisted living facilities, home care, and adult care.[81] Assisted living facilities are the most rapidly growing form of senior housing.[82] Panelists discussed several challenges in the market for long-term care, including consumer information and the role of competition.

A. Consumer Information

Long-term care facilities make varying degrees of information available to consumers. Marketing materials, contracts, websites and publications, tours of care facilities, and communications with residents and families are the principal means for disclosure of information.[83] Information regarding nursing homes is also available from public sources, including state and federal agencies.[84] Although these sources provide a considerable volume of information to consumers of nursing home care, panelists stated that much work remains to develop "ways to collect and present accurate, meaningful information that consumers can use."[85] One panelist observed that less information is available regarding assisted living facilities, and expressed concern about the reliability of the information that is disclosed.[86]

Panelists noted that it is difficult to provide consumer information regarding quality of long-term care because of difficulties defining and measuring "quality."[87] One panelist noted that

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[79] Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf.

[80] Thayer 6/11 at 147-48; Jan Thayer, *Assisted Living* 19 (6/11) (slides) [Thayer Presentation], *at* http://www.ftc.gov/ogc/healthcarehearings/docs/030611thayer.pdf; U.S. DEP'T OF HEALTH & HUMAN SERVICES, HIGH SERVICE OR HIGH PRIVACY ASSISTED LIVING FACILITIES, THEIR RESIDENTS AND STAFF: RESULTS FROM A NATIONAL SURVEY 1 (2000) [hereinafter HHS, ASSISTED LIVING SURVEY], *available at* http://aspe.hhs.gov/daltcp/reports/hshpes.htm.

[81] Thayer 6/11 at 141. Hospice care is also available to consumers with a terminal condition.

[82] HHS, ASSISTED LIVING SURVEY, *supra* note 80, at 1.

[83] Thayer 6/11 at 149; Thayer Presentation, *supra* note 80, at 22-24; Love 6/11 at 172; Keren Brown Wilson, *Assisted Living: Evolving Model for A New General of Elderly* 12-13 (6/11) [K. Wilson (stmt)], *at* http://www.ftc.gov/ogc/healthcarehearings/docs/030611wilson.pdf; Manard 6/11 at 175-76.

[84] *See* Centers for Medicare & Medicaid Services, Dep't of Health & Human Services, *Nursing Home Compare*, http://www.medicare.gov/NHCompare/home.asp (Page Last Updated Feb. 19, 2004).

[85] Manard 6/11 at 174-75; Edelman 6/11 at 188.

[86] Edelman 6/11 at 188; *see also* HHS, ASSISTED LIVING SURVEY, *supra* note 80, at 2.

[87] J. Lynn 5/30 at 178, 192-93; K. Wilson (stmt), *supra* note 83, at 15-16; Jan Thayer, *Written Statement of Jan Thayer On Behalf of The National Center for Assisted Living, Federal Trade Commission/Department of Justice, Hearing on Long Term Care/Assisted Living* 5 (6/11) [hereinafter Thayer (stmt)]; *see also* U.S. DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL,

consumers care about both quality of care and quality of life, but these terms mean different things to different people, and views on these subjects can change over time.[88] Panelists observed that consumer information must be usable, reliable, and relate to consumer values for it to have beneficial consequences.[89]

Several panelists stated that too much emphasis is currently placed on measures of quality that are prone to misinterpretation or that give an inaccurate picture of the quality of services provided.[90] One panelist pointed out that "almost every measure of quality in a care system will look better if the very sick die quickly."[91] Providers and regulatory agencies may also focus on attributes of quality (*e.g.*, safety) that are less significant to consumers than other attributes of quality (*i.e.*, dignity).[92] Panelists agreed that more research is necessary to link the quality measures collected by providers and regulatory agencies to quality of care and quality of life as experienced by consumers.[93] Panelists expressed concern that regulations required them to collect and disseminate information that was irrelevant to what consumers cared about (quality of care and quality of life).[94]

Panelists suggested several ways to improve mandated disclosure of information, consumer information, including the development of standardized quality measures,[95] greater consideration of the accessibility and usability of the information,[96] and enlisting the assistance of family members.[97] There was less agreement on the use of formal contracts to communicate information and address provider liability concerns ("negotiated risk

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NURSING HOME DEFICIENCY TRENDS AND SURVEY AND CERTIFICATION PROCESS CONSISTENCY (Mar. 2003).

[88] Thayer (stmt), *supra* note 87, at 5.

[89] *Id.* at 5-6; J. Lynn 5/30 at 176.

[90] K. Wilson (stmt), *supra* note 83, at 16; K. Wilson 6/11 at 163; Thayer (stmt), *supra* note 87, at 7; Manard 6/11 at 180.

[91] J. Lynn 5/30 at 196.

[92] K. Wilson (stmt), *supra* note 83, at 5-6, 16-17; K. Wilson 6/11 at 156-58; Thayer (stmt), *supra* note 87, at 7-8; Thayer 6/11 at 151-152.

[93] Thayer (stmt), *supra* note 87, at 7; *see also* Thayer 6/11 at 151; Manard 6/11 at 180; K. Wilson 6/11 at 162-63.

[94] Thayer (stmt), *supra* note 87, at 8; K. Wilson (stmt), *supra* note 83, at 17.

[95] Thayer (stmt), *supra* note 87, at 6; Thayer 6/11 at 150; Manard 6/11 at 176, 178; J. Lynn 5/30 at 178-79; Joanne Lynn, *Care to Count on When You Need It Most - Reforming Health Care Policy For Fatal Chronic Illness* 16 (5/30) (slides), *at* http://www.ftc.gov/ogc/healthcarehearings/docs/030530lynnjoanne.pdf.

Several panelists stated that consumers want more information on staffing patterns. Edelman 6/11 at 192-93; Paul 6/11 at 206-07; Love 6/11 at 218-19. One panelist suggested that the measures might include the suitability of the long-term care facility for consumers with a particular medical condition.

[96] Paul 6/11 at 203; Manard 6/11 at 178; *see also* Edelman 6/11 at 194-96; K. Wilson (stmt), *supra* note 83, at 7.

[97] K. Wilson (stmt), *supra* note 83, at 9; Thayer (stmt), *supra* note 87, at 8.

agreements"),[98] and on the effects of increased compensation for workers.[99]

B. *Competition in the Market for Long-Term Care*

There are a number of impediments to competition in the market for long-term care.[100] Many consumers are too sick, lack the time, or have insufficient information to shop around for nursing home care.[101] Consumers interested in assisted living facilities are less subject to these impediments, but less information is available for them to use. Medicare and Medicaid are dominant purchasers in the nursing home market; Medicaid covers more than two-thirds of residents and Medicare covers an additional 10 percent.[102] Medicaid plays a very small role and Medicare plays no role in the market for assisted living facilities.[103] One panelist complained that Medicare and Medicaid payment levels are so low that nursing homes discriminate against program beneficiaries when deciding who to admit.[104] Panelists and commentators have complained that CON restricts entry and protects incumbent providers. [105]

The Agencies applaud the disclosure of information to consumers in the market for long-term care. The Agencies urge states with CON programs involving long-term care facilities to reconsider whether they are best serving their citizens' health care needs by allowing these programs to continue.[106]

IV. INTERNATIONAL PERSPECTIVES

Introduction. All health care markets worldwide face the same triad of challenges: reducing health care costs, improving quality, and increasing access.[107]

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[98] Assisted Living Federation of America, *ALFA Releases Negotiated Risk Manual* (Apr. 3, 2000), *at* http://www.alfa.org/public/articles/details.cfm?id=119; Eric Carlson, *In the Sheep's Clothing of Resident Rights: Behind the Rhetoric of "Negotiated Risk,"* NAELA QUARTERLY, Spring 2003, at 1-2, *available at* http://www.nsclc.org/articles/neg_risk_naela.pdf; K. Wilson (stmt), *supra* note 83, at 7; *see also* K. Wilson 6/11 at 159-160; Edelman 6/11 at 219-20.

[99] K. Wilson (stmt), *supra* note 83, at 18; Edelman 6/11 at 196-97; *see also* Manard 6/11 at 184.

[100] J. Lynn 5/30 at 199; *see also* Thayer (stmt), *supra* note 87, at 7.

[101] J. Lynn 5/30 at 199; Manard 6/11 at 176.

[102] Manard 6/11 at 173-74.

[103] Thayer (stmt), *supra* note 87, at 8; Manard 6/11 at 182.

[104] Edelman 6/11 at 195-96 ("[D]iscrimination against Medicaid beneficiaries has been a common problem for decades.").

[105] Price 6/10 at 103 ("[I]t is a Certificate of Need process in Vermont that keeps the oligopoly in place."); *see also supra* notes 37-42, and accompanying text.

[106] *See supra* notes 37-42, and accompanying text.

[107] William M. Sage & Peter J. Hammer, *A Copernican View of Health Care Antitrust*, 65 LAW AND CONTEMP. PROB. 241, 248 (2002) ("[U]nderlying all health care systems are qualitatively similar problems, resources, and objectives."); Peter S. Hussey et al., *How Does the Quality of Care Compare in Five Countries*, 23 HEALTH AFFAIRS 89 (May/June 2004) (identifying quality problems in health care delivery worldwide); ORGANIZATION FOR ECONOMIC COOPERATION & DEVELOPMENT (OECD), TOWARDS HIGH-

Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing International Perspectives on Health Care and Competition Law and Policy on September 30.[108]

Most countries employ a mix of public and private financing and delivery systems, coupled with substantial regulation and subsidies.[109] Panelists agreed that competition law and policy play important but constrained roles in their countries.[110] Panelists also considered the significance of market concentration and consumer information in their respective countries.

A. International Perspectives on Competition and Health Care

In countries throughout the world, people regard health care as "special."[111] This perception has led many to argue that health care should not be subject to standard antitrust principles, or that special exemptions should be created.[112] One panelist observed that many in the health care field are more concerned with *why* competition laws are applied to health care, and not with *how* such laws should be applied.[113] More generally, competition is often viewed as irrelevant or even destructive to health care quality.[114] Efforts by antitrust agencies to bridge this gap have focused on education and outreach, but such efforts have proven difficult.[115] Antitrust agencies need to engage in ongoing competition advocacy to meet this challenge.[116]

B. Concentration of Health Care Markets

Health care markets worldwide are becoming increasingly concentrated.[117] Concentration can result in cost efficiencies and economies of scale, but more concentrated markets pose greater risks to

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PERFORMING HEALTH SYSTEMS (2004).

[108] Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcare hearings/completeagenda.pdf.

[109] M. Jacobs 9/30 at 79-80; Purcell 9/30 at 56; Bhojani 9/30 at 13, 101.

[110] *See* Purcell 9/30 at 74-75; Bhojani 9/30 at 16-17; M. Jacobs 9/30 at 87. Representatives of the competition agencies of Australia, Ireland and Taiwan testified at the Hearings.

[111] Purcell 9/30 at 74-75, 91-93.

[112] Bhojani 9/30 at 17, 25-28; B. Cooper 9/30 at 38-39.

[113] Bhojani 9/30 at 16-17.

[114] Purcell 9/30 at 67, 74-75; M. Jacobs 9/30 at 86.

[115] Bhojani 9/30 at 16-19; Purcell 9/30 at 56; M. Jacobs 9/30 at 87 (challenges to antitrust enforcement include "widespread professional and, to a lesser extent perhaps, social opposition").

[116] M. Jacobs 9/30 at 85-88; Purcell 9/30 at 74-75.

[117] Liu 9/30 at 52-53 (noting concentration of hospital markets and medical groups in Taiwan); Purcell 9/30 at 61, 64-66 (noting concentration in health insurance markets in Ireland); M. Jacobs 9/30 at 81-82 (noting concentration in multiple health care financing and delivery markets in Australia and U.S.).

competition.[118] In addition, regulation can easily create barriers to entry, which is likely to worsen market concentration.[119]

C. *Consumer Information in Health Care Markets*

Consumer information is a problem in health care markets worldwide. Lack of information is a significant problem for many consumers.[120] Restrictions on truthful advertising create further barriers to information flow.[121] In some instances, however, consumers also face an oversupply of information and a paucity of resources to compare such information.[122] Some countries have sought to address these problems with standardized disclosures and brochures.[123] Consumer information presents challenges for competition agencies, governments, providers, and individual consumers throughout the world.

V. REMEDIES

Introduction. Competition law is only as good as the remedies it imposes. An effective remedy must resolve the anticompetitive harm, restore competition, and prevent future anticompetitive conduct.[124] Optimal enforcement must steer between over-deterrence and under-deterrence. Over-deterrence may occur if conduct that is not, in fact, anticompetitive is challenged, or if excessive sanctions are imposed on anticompetitive conduct.[125]

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[118] M. Jacobs 9/30 at 82. *See also supra* Chapter 3.

[119] Purcell 9/30 at 65-66 ("However necessary risk equalization might be, it undoubtedly represents a barrier to entry to the health insurance market, as, of course, does the uncertainty about how the whole scheme will operate.").

[120] M. Jacobs 9/30 at 83 ("[I]n many markets, there is almost no information at all."). *See also supra* Chapter 1.

[121] Purcell 9/30 at 107. *See also supra* Chapter 7.

[122] B. Cooper 9/30 at 32 ("There's actually a lot of information out there. So consumers actually have to deal with perhaps an oversupply of information, but it's very difficult to compare the products of different funds the way the information is presented. They're comparing apples with oranges and it makes life very hard."); M. Jacobs 9/30 at 83.

[123] B. Cooper 9/30 at 32; Purcell 9/30 at 75.

[124] *See* Robert Pitofsky, *Antitrust at the Turn of the Twenty-First Century: The Matter of Remedies*, 91 GEORGETOWN L.J. 169, 170 (2002) ("Broadly speaking, the principal goals of antitrust should be first, to deter anticompetitive conduct, adjusting for the fact that much illegal conduct is not detected; and second, to take illegal gains away from the law violators and restore those monies to the victims.") *See also* Kursh 10/1 at 5-6 ("First and foremost, the remedy must resolve the competitive problem. The only legitimate goal of a civil antitrust remedy, whether in a merger or a civil non-merger context, is to restore competition to the marketplace . . . . A second guiding principle [is that] [t]here must be a close, logical nexus between the remedy and the alleged violation . . . . The third guiding principle is . . . that the remedy should promote competition and not competitors . . . . And finally, but very importantly, the remedy must be enforceable.").

[125] *See* X PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1741c, at 160 (2d ed. 2004) ("[F]urther inquiry may be inadvisable because its expense or high error rate would significantly deter desirable business behavior without significantly deterring anticompetitive behavior . . . This screening rationale applies . . . to rule of reason inquiry because the litigation costs and risks of error under that approach may exceed the benefits of inquiry for many categories of cases."); Roxane C. Busey, American Bar Ass'n, *Commission's Request for Comment on Remedial*

Under-deterrence may occur if anticompetitive conduct is not identified and addressed, or if inadequate remedies are imposed in response to such conduct.[126] The Agencies must avoid both of these extremes to effect optimal deterrence, while recognizing that bringing cases helps create a "compliance norm."[127] As noted previously, the Agencies have brought almost twenty cases in the past two years against providers allegedly engaged in anticompetitive conduct.

Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing Competition Law and Remedies: Civil/Criminal on October 1.[128] Panelists disagreed on whether the Agencies are over-deterring or under-deterring anticompetitive conduct in the health care marketplace.[129]

A. Civil Antitrust Remedies

Civil remedies come in two basic types (structural and conduct) and are applied to two types of cases (merger and non-merger). Enforcement officials must assess whether the remedy should change the structure of the industry, regulate the conduct of the affected firms, or do both.[130]

Structural remedies, which require the divestiture of some assets to preserve competition, are more common in merger cases.[131] There is typically little need for post-divestiture oversight because the divestiture generally restores competition to the pre-merger level.[132] Because conduct remedies can be difficult to formulate, require ongoing oversight, and may be difficult to modify in response to changed circumstances, they are used less frequently in merger cases.[133]

The Agencies rarely seek dissolution.

Use of Disgorgement (Public Comment) (noting concern with duplicative liabilities and recoveries).

[126] *See, e.g.*, Pfizer, Inc. v. Government of India, 434 U.S. 308, 315 (1978) (If plaintiffs are "not permitted to seek remedy for their antitrust injuries, persons doing business both in this country and abroad might be tempted to enter into anticompetitive conspiracies . . . ."). *See* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE §17 (2d ed. 1999); WILLIAM BREIT & KENNETH G. ELZINGA, ANTITRUST PENALTY REFORM: AN ECONOMIC ANALYSIS (1986).

[127] *See generally* TOM R. TYLER, WHY PEOPLE OBEY THE LAW (1990).

[128] Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcare hearings/completeagenda.pdf.

[129] *Compare* Bierig 10/1 at 70-72 and 109-113, *with* Grady 10/1 at 56-60 and 116.

[130] O'Connor 10/1 at 24; Kursh 10/1 at 7.

[131] Federal and State enforcers must balance competing interests and concerns in arriving at the appropriate structural remedy. *See, e.g.*, Donahue 10/1 at 34-44. The enjoining of a proposed merger also constitutes a structural remedy.

[132] O'Connor 10/1 at 26 ("The economists, of course, tell us that structural remedies change the incentive structure of the firms, and that compliance is more likely with structural remedy than with conduct remedies that require substantially more judicial oversight."); Kursh 10/1 at 7-8.

[133] An injunction barring some behavior may put a firm at a disadvantage in reacting to unforseen changes in the market. Kursh 10/1 at 7-9; O'Connor 10/1 at 26 ("For example, there is general agreement that divestiture is preferred in merger cases.").

As the Commission wrote in its decision in *Indiana Federation of Dentists*, dissolution is appropriate "only in circumstances where there is no significant function remaining for an organization other than to repeat the antitrust violations or in which a conduct order would not reasonably be expected to prevent repeating such violations."[134] Both Agencies have settled a number of cases by requiring the dissolution of the entity that facilitated alleged anticompetitive conduct.[135]

Civil non-merger cases involve a far broader range of settings and conduct.[136] The Agencies have typically focused on enjoining the conduct in question – a strategy described by panelists and commentators as "go and sin no more."[137] In some instances, relief is also sought against consultants and other parties who planned or enabled the anticompetitive conduct.[138] "Fencing-in provisions" are sometimes used to prevent recurrence.[139] The Agencies have also required parties to terminate or modify contracts,[140] and generate written reports regarding compliance efforts.[141]

On rare occasions, disgorgement is sought as well.[142] Disgorgement is an equitable remedy, designed to deprived the wrongdoer of his unjust enrichment and to deter others from future violations. The Commission's policy statement on

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[134] FTC v. Indiana Fed'n of Dentists, 101 F.T.C. 57 (1986). *See also* III PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 653c, at 100 (2d ed. 2002) ("The strongest arguments for dissolution, divestiture, or other structural relief dissipating the monopolist's power are deterrence-based. Such remedies are intended to prevent a recurrence of § 2 violations by making the defendant unable to engage in them.").

[135] United States v. Mountain Health Care, P.A. 2003-2 Trade Cas. (CCH) P74,162, *appeal dismissed* 2004 U.S. App. LEXIS 8641 (4th Cir. 2004); *In re* Carlsbad Physician Ass'n, No. C-4081 (May 2, 2003) (agreement containing consent order to cease and desist), *available at* http://www.ftc.gov/os/2003/05/carlsbadagree.pdf; *In re* Obstetrics and Gynecology Med. Corp. of Napa Valley, No. C-4048 (May 14, 2002) (decision and order), *available at* http://www.ftc.gov/os/2002/05/obgyndo.pdf.

[136] Kursh 10/1 at 9 ("[C]ivil non-merger antitrust violations appear in infinite variety.").

[137] O'Connor 10/1 at 31; David Marx Jr., *Messenger Models: What Can the Agencies do to Prevent Provider Networks from Violating the Antitrust Laws?*, HEALTH LAW NEWS, April 2004, at 25. *See also* Singer 10/1 at 49 ("The core remedies have been the typical cease and desist, don't do it any more remedies ....").

[138] *See In re* Me. Health Alliance, No. C-4095 (Aug. 27, 2003) (decision and order), *available at* http://www.ftc.gov/os/2003/08/mainehealthdo.pdf; *In re* Physician Network Consulting, No. C-4094 (Aug. 27, 2003) (decision and order), *available at* http://www.ftc.gov/os/2003/08/physnetworkdo.pdf; *In re* Aurora Assoc'd Primary Care Physicians, No. 011 0174 (May 9, 2002) (complaint), *available at* http://www.ftc.gov/os/2002/05/auroracmp.pdf; Press Release, U.S. Dep't of Justice, Florida Physicians Agree to Stop Illegal Joint Negotiations in Response to Justice Department Lawsuit (Jan. 26, 1999), *at* http://www.usdoj.gov/atr/public/press_releases/1999/2196.htm.

[139] Kursh 10/1 at 10; Singer 10/1 at 49. Such provisions may prohibit even lawful conduct, depending on the facts of the case and nature of the harm and the market.

[140] Kursh 10/1 at 11.

[141] Kursh 10/1 at 11.

[142] Federal Trade Comm'n, *Policy Statement on Monetary Equitable Remedies in Competition Cases*, 68 FR 45820, 45821 (2003) [hereinafter FTC, *Monetary Equitable Remedies*].

disgorgement outlines three factors that it will consider when evaluating use of this remedy.[143] Three years ago, the Commission pursued disgorgement in a monopolization case in the healthcare industry, and secured a settlement with Mylan Labs, Inc., of $100 million.[144]

Panelists debated the propriety of disgorgement in health care cases. One panelist stated that disgorgement will be difficult to obtain because financial harm to consumers often cannot be quantified.[145] Another panelist believed disgorgement should be employed more frequently to deter anticompetitive conduct.[146] One panelist and commentators stated that the frequency of alleged physician price fixing cases indicates that physicians are insufficiently deterred by existing remedies.[147] Another panelist observed, however, that the Commission is unlikely to seek disgorgement unless there was a clear violation of the law that was "on all fours with existing precedent."[148] The Agencies will carefully consider whether disgorgement is appropriate in all future cases.

Remedies may also have significant consequences in other markets. Commentators have found that the announcement of a Commission enforcement action against an advertiser has a significant impact on the advertiser's share price.[149] Being the target of an enforcement action is unlikely to enhance a provider's reputation.[150]

B. Criminal Antitrust Remedies

Some antitrust violations can give rise to criminal sanctions. As noted previously, the Division has exclusive jurisdiction over enforcement of federal criminal antitrust statutes. There have been only a few criminal health care antitrust cases.[151] One panelist suggested that criminal enforcement is inappropriate because physicians do not understand the antitrust laws, and do not intend to violate

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[143] FTC, *Monetary Equitable Remedies*, *supra* note 142. The three factors are that: (1) the underlying violation must be clear; (2) there must be a reasonable basis for calculating the amount of remedial payment; and (3) the value of seeking disgorgement will be considered in light of other remedies available in the matter, including private actions and criminal proceedings. *Id.*

[144] FTC v. Mylan Labs, Inc., Cv. 98-3114 (TFH) (D.D.C. Feb. 9, 2001) (alleged monopolization; stipulated judgment included $100 million restitution); *see* Mem. Opinion, 62 F. Supp. 2d 25, 36-37 (D.D.C. 1999), *revised and reaffirmed in pertinent part*, 99 F. Supp. 2d 1, 4-5 (D.D.C. 1999).

[145] Bierig 10/1 at 118.

[146] Grady 10/1 at 115-16.

[147] *Id.* at 116 ("[T]he reason they haven't gotten the message is I don't think they're frankly scared enough."); Marx, *supra* note 137, at 28.

[148] Orlans 10/1 at 116-117.

[149] *See* Sam Peltzman, *The Effects of FTC Advertising Regulation*, 24 J.L. & ECON. 403 (1981); Alan Mathios & Mark Plummer, *The Regulation of Advertising by the Federal Trade Commission: Capital Market Effects*, 12 RES. L. & ECON. 77 (1989).

[150] Health care providers are greatly concerned with their reputations. *See* William M. Sage, *Reputation, Malpractice Liability, and Medical Error*, *in* ACCOUNTABILITY: PATIENT SAFETY AND POLICY REFORM (Virginia A. Sharpe, ed., 2004).

[151] Grady 10/1 at 53-56; Greaney 9/10/02 at 313.

them.[152] Other panelists dismissed this claim, and stated that both physicians and their consultants should face criminal sanctions in appropriate cases.[153] The Division is continuing to consider carefully the appropriateness of criminal sanctions in particular health care cases.

Conclusion. Remedies are a critical issue in implementing an effective competition policy. If remedies are inadequate, they will not have a credible deterrent effect. If remedies are excessive, they will over-deter, and discourage conduct that is actually permissible. Balancing these considerations is a difficult task.

The Agencies view all anticompetitive conduct as serious, and will seek appropriate sanctions in light of the considerations outlined previously. In general, much more stringent measures are necessary against those who violate the antitrust laws repeatedly or flagrantly and those who facilitate anticompetitive conduct by multiple parties. The Division will also pursue criminal sanctions in appropriate cases. Disgorgement and/or dissolution will be sought in appropriate cases.

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[152] Bierig 10/1 at 68.

[153] Grady 10/1 at 54-55, 94-95; O'Connor 10/1 at 103-04.